NIH PROBLEM REPORT FORM

Use this form to report problems to the IRB that may be:

A. Unanticipated Problems (UPs) including Unanticipated Adverse Device Effects (UADEs)
B. Protocol Deviations (PDs) or
C. Non-compliance

For more information on UPs and PDs, see SOP 16**,** "Principal Investigator (PI) and IRB Reporting Requirements for Unanticipated Problems and Protocol Deviations". For more information on Non-compliance, see SOP 16A**,** "Allegations and Incidents of Non-compliance with the Requirements of the NIH Human Research Protection Program (HRPP)."

DEFINITIONS

Protocol Deviation (PD): Any change, divergence, or departure from the IRB-approved research protocol.

The impact of a PD is characterized by designation as serious or not serious (see SOP 16- Appendix E.) PDs include three types of protocol deviations:

A. Those that occur because a member of the research team deviates from the protocol;

B. Those that are identified before they occur, but cannot be prevented (e.g., when a subject alerts the research team that inclement weather will prevent the subject from attending a scheduled protocol visit); and

C. Those that are discovered after they occur.

Unanticipated Problem (UP): Is any incident, experience, or outcome that meets **all** of the following criteria:

A. **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the

IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

B. **Related or possibly related** to participation in the research (**possibly related** means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

C. Suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Non-compliance: The failure to comply with applicable NIH HRPP policies, IRB requirements, or regulatory requirements for the protection of human research subjects; (See SOP 16A, "Allegations and Incidents of Non-compliance with the Requirements of the NIH Human Research Protection Program (HRPP).")

Minor non-compliance: Non-compliance that, is neither serious nor continuing.

Serious: A UP or PD is serious if it meets the definition of a Serious Adverse Event***** or if it compromises the safety, welfare or rights of subjects or others**.**

* **Serious Adverse Event (SAE):** is any Adverse Event that: 1. Results in death; 2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred); 3. Results in inpatient hospitalization or prolongation of existing hospitalization; 4. Results in a persistent or significant disability/incapacity; 5. Results in a congenital anomaly/birth defect; or 6. Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

INSTRUCTIONS TO PRINCIPAL INVESTIGATORS

A. Use this form to report all problems to the IRB including UPs, PDs, or Non-compliance

B. Use the appropriate electronic IRB system to complete this form (iRIS or PTMS.) If the PI is unable to access the appropriate IRB reporting system, PI may use

this NIH Problem Report Form. The PI may elect also to report events (especially if Serious) to the IRB Chair/designee and/or the CD, in person or by phone or e-mail. However, such reporting is in addition to the required reporting using the NIH Problem Report Form.

C. Any modifications to the protocol and/or consent(s) resulting from a UP, PD or Non-compliance must be submitted via a separate amendment in the appropriate IRB system (iRIS or PTMS), except when necessary to eliminate apparent immediate hazard to the subjects as explained in SOP 10 – "Amendments to IRB-approved Research".

D. Additional reporting requirements may apply, e.g., to the FDA, the NIH Office of Biotechnology Activities (OBA).

IMPORTANT: Notify the IRB and Clinical Director using the following timeframes:

A. **Serious UPs, UADEs, Serious PDs, and Serious Non-compliance:** as soon as possible, but not more than seven (7) days after the PI first learns of the event.

B. **Not Serious UP, Not Serious PD or Minor Non-compliance:** not more than fourteen (14) days after the PI first learns of the event.

NIH PROBLEM REPORT FORM

Protocol #:	**Protocol Title:**
System Ref#: [IRB system generated]	**Report version:** *(select one)* ☐ **Initial Report** ☐ **Revised Report** ☐ **Follow-up** **If revised report or follow-up, Original System Ref #:** _____
Principal Investigator: [system pull based on NED ID]	**Institute:** **Office Phone:** **E-mail:**
FDA Regulated Research: [system pull from IRB system]	**Study Sponsor**: _____ **IND/IDE#** _____ **IND/IDE Name:** _____
Date of problem: mm/dd/yyy	**Location of problem:** *(e.g., NIH Clinical Center or Name of Site/Location)* ☐ **NIH CC** ☐ **Other, specify:** _____
Who identified the problem? *(provide role: nurse, investigator, monitor, etc…)*	

Brief Description of Subject: *(if applicable)* (*Do NOT include personal identifiers)*	**Sex:** ☐ **Male** ☐ **Female** **Age:** ☐ **Not applicable (more than subject is involved)**

Diagnosis under study:

If the subject is enrolled on any other studies, list the protocol number(s) here: *(If applicable, submit a separate report form for each protocol listed)*

Is this problem? (*select all that apply*)

☐ **An Unanticipated Problem that is:** ☐ **Serious** ☐ **Not Serious**

☐ **A Protocol Deviation that is:** ☐ **Serious** ☐ **Not Serious**

☐ **Non-compliance**

Is the problem also *(select all that apply)*

☐ **AE**

☐ **Non-AE**

Name the problem: *(select all that apply)*

☐ **Adverse drug reaction**

☐ **Abnormal lab value**

☐ **Death**

☐ **Cardiac Arrest/ code**

☐ **Anaphylaxis**

☐ **Sepsis/Infection**

☐ **Blood product reaction**

☐ **Unanticipated surgery/procedure**

☐ **Change in status (e.g. increased level of care required)**

☐ **Allergy (non-medication)**

☐ **Fall**

☐ **Injury/Accident (not fall)**

☐ **Specimen collection issue**

☐ **Informed consent issue**

☐ **Ineligible for enrollment**

☐ **Breach of PII**

☐ **Tests/procedures not performed on schedule**

☐ **Other, brief 1-2 word description: _____**

Detailed Description of the problem: (*Include any relevant treatment, outcomes or pertinent history*):

Is this problem unexpected? *(i.e., event not described in protocol, consent, or Investigator Brochure)* ☐ **YES** ☐ **NO Please explain:**

Is this problem related or possibly related to participation in the research? ☐ **YES** ☐ **NO**

Please explain:

Does the problem suggest the research places subjects or others at a greater risk of harm? ☐ **YES** ☐ **NO** **Please explain:**

Have similar problems occurred on this protocol? ☐ **YES** ☐ **NO**

If "Yes", how many? ____ **Please describe:**

Describe what steps have you already taken as a result of this problem?

What steps do you plan to take as a result of the problem? (*select all that apply*)

☐ **No action required**

☐ **Amend consent** (*Separate amendment submission required*)

☐ **Amend protocol** (*Separate amendment submission required*)

☐ **Inform existing subjects** (*Include example of information to be provided to subjects*)

☐ **Close the protocol** (*Separate closure submission required*)

☐ **Temporarily halt the protocol** (*Provide plan for management of enrolled subjects*)

☐ **Increase frequency/type of safety or other monitoring** (Separate amendment submission required)

☐ **Other corrective action, describe:**

In addition to the IRB, this problem is also being reported to: (*select all that apply*)

☐ **IC Clinical Director**

☐ **Study Sponsor**

☐ **If Investigator-held IND/IDE, report to FDA**

☐ **Manufacturer :** ____________________

☐ **Institutional Biosafety Committee**

☐ **Office of Biotechnology Activities**

☐ **Data Safety Monitoring Board**

☐ **CC Occurrence Reporting System (ORS)**

☐ **Other:** ____________________________________

☐ **None of the above applicable**

INVESTIGATOR'S SIGNATURE:	**DATE:** mm/dd/yyyy
MEDICAL ADVISORY INVESTIGATOR'S SIGNATURE: *(if applicable)*	**DATE:** mm/dd/yyyy
CLINICAL DIRECTOR: *(If a UP, UADE, or a Serious PD)*	**DATE :** mm/dd/yyyy

– –

IRB Use Only

IRB Determination

System Ref# : [IRB system generated]

Date IRB received: [IRB system generated]

Date of IRB review: [IRB system generated]

Select the IRB's determination below: (*select all that apply*)

Unanticipated Problem (UP), confirm that the following 3 criteria are met: (*Report to OHSRP*)

- ☐ **Unexpected**
- ☐ **Related or possibly related to research**
- ☐ **Suggests greater risk of harm to subjects or others**

If any of the above are not selected, explain: _____

UP: (*select one*)

- ☐ **Serious**
- ☐ **Not Serious**

Non-compliance: (select all that apply)

- ☐ **Serious (*Report to OHSRP*)**
- ☐ **Continuing (*Report to OHSRP*)**
- ☐ **Not serious or continuing**

Protocol Deviation: (*select one*)

- ☐ **Serious**
- ☐ **Not Serious**

IRB meeting minutes:

Indicate the IRB's action in response to this event: *(specify time frames where applicable if not already addressed in the minutes)*

☐ **No action required**

☐ **Follow-up report required: _____**

☐ **Amend consent(s)/assent(s): _____**

☐ **Amend protocol: _____**

☐ **Inform existing subjects: _____**

☐ **Increase frequency/type of safety or other monitoring**

☐ **More frequent continuing review, specify review period: _____**

☐ **Suspend the protocol:_____** (*Report to OHSRP*)

☐ **Terminate the protocol: _____** (*Report to OHSRP*)

☐ **Other corrective action, describe: _____**

_ _

OHSRP Use Only [OHSRP editable]

Date OHSRP received the preliminary report: [OHSRP system generated]

__/__/__

Date IRB determination report received: [OHSRP system generated]

__/__/__

This event is presumed to be :

☐ **Possible UP**

☐ **Possible Non-compliance**

Date first reported to OHRP: __/__/____

Date final report to OHRP, no stips: __/__/____

Date of final report, IRB follow-up: __/__/__

OHSRP Notes: _____

OHRP Response Date: __/__/___

OHRP Comments :